

Union Calendar No. 354

113TH CONGRESS
2^D SESSION

H. R. 1281

[Report No. 113-478]

To amend the Public Health Service Act to reauthorize programs under part A of title XI of such Act.

IN THE HOUSE OF REPRESENTATIVES

MARCH 20, 2013

Ms. ROYBAL-ALLARD (for herself and Mr. SIMPSON) introduced the following bill; which was referred to the Committee on Energy and Commerce

JUNE 19, 2014

Additional sponsors: Ms. MOORE, Mr. GRIJALVA, Mr. WAXMAN, Mr. ROGERS of Kentucky, Mr. HIGGINS, Mr. RANGEL, Ms. LEE of California, Ms. SPEIER, Mr. MCGOVERN, Mrs. CAPPS, Ms. JACKSON LEE, Mr. HASTINGS of Florida, Ms. MCCOLLUM, Mr. DAVID SCOTT of Georgia, Ms. CLARKE of New York, Mr. CONYERS, Mr. DINGELL, Mr. HUFFMAN, Ms. DELAURO, Mr. CROWLEY, Mr. COHEN, Ms. SLAUGHTER, Mr. BISHOP of Georgia, Ms. CASTOR of Florida, Mr. TAKANO, Ms. WILSON of Florida, Mr. LOEBSACK, Mr. BERA of California, Mr. WALDEN, Mr. NADLER, Mr. GENE GREEN of Texas, Mr. DELANEY, Mr. COLLINS of New York, Mr. POCAN, Mr. HECK of Washington, Mr. FARR, Mr. MATHESON, Mrs. BEATTY, Mrs. KIRKPATRICK, Mr. MORAN, Mr. SIRES, Ms. SCHAKOWSKY, Mr. COSTA, Ms. LORETTA SANCHEZ of California, Mr. RUIZ, Mrs. NEGRETE MCLEOD, Mr. CASTRO of Texas, Mr. GALLEGO, Mr. BECERRA, Mr. SABLAN, Ms. MICHELLE LUJAN GRISHAM of New Mexico, Mr. CÁRDENAS, Mr. GUTIÉRREZ, Mr. RYAN of Ohio, Mr. BEN RAY LUJÁN of New Mexico, Mr. GARCIA, Mr. HINOJOSA, Mrs. NAPOLITANO, Mr. VARGAS, Mr. SERRANO, Ms. VELÁZQUEZ, Mr. KING of New York, Mrs. CAPITO, Mr. CALVERT, Mr. ROYCE, Mr. GRAYSON, Ms. ESTY, Mr. GARY G. MILLER of California, Mr. JONES, Mr. MCKEON, Mr. PIERLUISI, Mr. SCHIFF, Mr. NEAL, Mr. LANGEVIN, Mr. DOYLE, Mr. TONKO, Ms. WASSERMAN SCHULTZ, Ms. DEGETTE, Ms. ESHOO, Mrs. LOWEY, Mr. BARTON, Mr. DANNY K. DAVIS of Illinois, Mr. GARAMENDI, Mr. McDERMOTT, Mr. NUNES, Mr. COURTNEY, Mr. LEVIN, Mr. CICILLINE, Mr. WELCH, Mr. BLUMENAUER, Ms. TITUS, Mr. LIPINSKI, Mr. TIERNEY,

Mr. LARSON of Connecticut, Ms. MATSUI, Ms. GRANGER, Mr. LATHAM, Mrs. CHRISTENSEN, Mr. LANCE, Mr. ELLISON, Mr. HONDA, Ms. SHEA-PORTER, Ms. BROWNLEY of California, Ms. EDWARDS, Mr. MEEKS, Mr. MICHAUD, Ms. EDDIE BERNICE JOHNSON of Texas, Mr. PAYNE, Mr. PALLONE, Mr. JOHNSON of Georgia, Mr. LOWENTHAL, Mr. THOMPSON of California, Mr. CLAY, Mr. CARTWRIGHT, Ms. SCHWARTZ, Mr. PASCRELL, Mr. BURGESS, Mrs. MCMORRIS RODGERS, and Mr. ISRAEL

JUNE 19, 2014

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed

[Strike out all after the enacting clause and insert the part printed in *italie*]

[For text of introduced bill, see copy of bill as introduced on March 20, 2013]

A BILL

To amend the Public Health Service Act to reauthorize programs under part A of title XI of such Act.

1 *Be it enacted by the Senate and House of Representa-*
 2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) *SHORT TITLE.*—*This Act may be cited as the*
 5 *“Newborn Screening Saves Lives Reauthorization Act of*
 6 *2014”.*

7 (b) *TABLE OF CONTENTS.*—*The table of contents of this*
 8 *Act is as follows:*

Sec. 1. Short title; table of contents.

Sec. 2. Improved newborn and child screening and followup for heritable dis-
orders.

Sec. 3. Evaluating the effectiveness of newborn and child screening and followup
programs.

Sec. 4. Advisory Committee on Heritable Disorders in Newborns and Children.

Sec. 5. Clearinghouse of Newborn Screening Information.

Sec. 6. Laboratory quality and surveillance.

Sec. 7. Interagency Coordinating Committee on Newborn and Child Screening.

Sec. 8. National contingency plan for newborn screening.

Sec. 9. Hunter Kelly Research Program.

Sec. 10. Authorization of appropriations.

Sec. 11. Reports to Congress.

9 **SEC. 2. IMPROVED NEWBORN AND CHILD SCREENING AND**
 10 **FOLLOWUP FOR HERITABLE DISORDERS.**

11 *Section 1109 of the Public Health Service Act (42*
 12 *U.S.C. 300b–8) is amended—*

13 (1) *in subsection (a)—*

14 (A) *in the matter preceding paragraph*

15 (1)—

16 (i) *by striking “subsection (j)” and in-*
 17 *serting “section 1117”; and*

18 (ii) *by striking “and in consultation*
 19 *with the Advisory Committee” and insert-*

1 ing “and taking into consideration the ex-
2 pertise of the Advisory Committee”;

3 (B) by amending paragraph (2) to read as
4 follows:

5 “(2) to assist in providing health care profes-
6 sionals and newborn screening laboratory personnel
7 with education in newborn screening, counseling, and
8 training in—

9 “(A) relevant and new technologies in new-
10 born screening and congenital, genetic, and met-
11 abolic disorders;

12 “(B) the importance of the timeliness of col-
13 lection, delivery, receipt, and screening of speci-
14 mens; and

15 “(C) sharing of medical and diagnostic in-
16 formation with providers and families;”;

17 (C) in paragraph (3), by striking “and” at
18 the end;

19 (D) in paragraph (4)—

20 (i) by striking “treatment” and insert-
21 ing “followup and treatment”; and

22 (ii) by striking the period and insert-
23 ing “; and”; and

24 (E) by adding at the end the following:

25 “(5) to improve the timeliness of—

1 “(A) the collection, delivery, receipt, and
2 screening of specimens; and

3 “(B) the diagnosis of heritable disorders in
4 newborns.”;

5 (2) in subsection (c), by striking “application
6 submitted for a grant under subsection (a)(1)” and
7 inserting “application for a grant under this sec-
8 tion”;

9 (3) in subsection (h), by striking “application
10 submitted under subsection (c)(2)” each place it ap-
11 pears and inserting “application for a grant under
12 this section”; and

13 (4) by striking subsection (j) (relating to author-
14 ization of appropriations).

15 **SEC. 3. EVALUATING THE EFFECTIVENESS OF NEWBORN**
16 **AND CHILD SCREENING AND FOLLOWUP PRO-**
17 **GRAMS.**

18 Section 1110 of the Public Health Service Act (42
19 U.S.C. 300b–9) is amended—

20 (1) in the section heading, by inserting “**AND**
21 **FOLLOWUP**” after “**CHILD SCREENING**”;

22 (2) in subsection (a), by striking “of screening,”
23 and inserting “, including with respect to timeliness,
24 of screening, followup,”;

25 (3) in subsection (b)—

1 (A) in paragraph (1)—

2 (i) by striking “counseling, testing”
3 and inserting “treatment, counseling, test-
4 ing, followup,”; and

5 (ii) by inserting before the semicolon
6 the following: “, including, as appropriate,
7 through the assessment of health and devel-
8 opment outcomes for such children through
9 adolescence”;

10 (B) in paragraph (2)—

11 (i) by striking “counseling, testing”
12 and inserting “treatment, counseling, test-
13 ing, followup,”;

14 (ii) by inserting “in a timely manner”
15 after “in newborns and children”; and

16 (iii) by striking “or” at the end;

17 (C) in paragraph (3), by striking the period
18 at the end and inserting a semicolon; and

19 (D) by adding at the end the following:

20 “(4) methods that may be identified to improve
21 quality in the diagnosis, treatment, and disease man-
22 agement of heritable disorders based on gaps in serv-
23 ices or care; or

1 “(5) methods or best practices by which the eligi-
2 ble entities described in section 1109 can achieve in
3 a timely manner—

4 “(A) collection, delivery, receipt, and screen-
5 ing of newborn screening specimens; and

6 “(B) diagnosis of heritable disorders in
7 newborns.”; and

8 (4) by striking subsection (d) (relating to author-
9 ization of appropriations).

10 **SEC. 4. ADVISORY COMMITTEE ON HERITABLE DISORDERS**
11 **IN NEWBORNS AND CHILDREN.**

12 Section 1111 of the Public Health Service Act (42
13 U.S.C. 300b–10) is amended—

14 (1) in subsection (b)—

15 (A) by redesignating paragraphs (4)
16 through (6) as paragraphs (6) through (8), re-
17 spectively;

18 (B) by inserting after paragraph (3), the
19 following:

20 “(4) provide technical assistance, as appropriate,
21 to individuals and organizations regarding the sub-
22 mission of nominations to the uniform screening
23 panel, including prior to the submission of such
24 nominations;

1 “(5) take appropriate steps, at its discretion, to
2 prepare for the review of nominations prior to their
3 submission, including for conditions for which a
4 screening method has been validated but other nomi-
5 nation criteria are not yet met, in order to facilitate
6 timely action by the Advisory Committee once such
7 submission has been received by the Committee;”;

8 (C) in paragraph (6) (as so redesignated),
9 by inserting “, including the cost” after “public
10 health impact”; and

11 (D) in paragraph (8) (as so redesignated)—

12 (i) in subparagraph (A), by striking
13 “achieve rapid diagnosis” and inserting
14 “achieve best practices in rapid diagnosis
15 and appropriate treatment”;

16 (ii) in subparagraph (D), by inserting
17 before the semicolon “, including informa-
18 tion on cost and incidence”;

19 (iii) in subparagraph (J), by striking
20 “and” at the end;

21 (iv) in subparagraph (K), by striking
22 the period and inserting “; and”; and

23 (v) by adding at the end the following:

24 “(L) the timeliness of collection, delivery,
25 receipt, and screening of specimens to be tested

1 *for heritable disorders in newborns in order to*
2 *ensure rapid diagnosis and followup.”;*

3 (2) *in subsection (d)—*

4 (A) *in paragraph (1)—*

5 (i) *by striking “180” and inserting*
6 *“120”; and*

7 (ii) *by adding at the end the following:*

8 *“If the Secretary is unable to make a deter-*
9 *mination to adopt or reject such rec-*
10 *ommendation within such 120-day period,*
11 *the Secretary shall notify the Advisory*
12 *Committee and the appropriate committees*
13 *of Congress of such determination together*
14 *with an explanation for why the Secretary*
15 *was unable to comply within such 120-day*
16 *period, as well as a plan of action for con-*
17 *sideration of such pending recommenda-*
18 *tion.”;*

19 (B) *by striking paragraph (2);*

20 (C) *by redesignating paragraph (3) as*
21 *paragraph (2); and*

22 (D) *by adding at the end the following:*

23 *“(3) DEADLINE FOR REVIEW.—For each condi-*
24 *tion nominated to be added to the recommended uni-*
25 *form screening panel in accordance with the require-*

1 *ments of this section, the Advisory Committee shall*
2 *review and vote on the nominated condition within 9*
3 *months of the date on which the Advisory Committee*
4 *referred the nominated condition to the condition re-*
5 *view workgroup.”;*

6 *(3) by redesignating subsections (f) and (g) as*
7 *subsections (g) and (h), respectively;*

8 *(4) by inserting after subsection (e) the following*
9 *new subsection:*

10 *“(f) MEETINGS.—The Advisory Committee shall meet*
11 *at least 4 times each calendar year, or at the discretion*
12 *of the Designated Federal Officer in consultation with the*
13 *Chair.”;*

14 *(5) by amending subsection (g) (as so redesign-*
15 *ated) to read as follows:*

16 *“(g) CONTINUATION OF OPERATION OF COMMITTEE.—*

17 *“(1) IN GENERAL.—Notwithstanding section 14*
18 *of the Federal Advisory Committee Act, the Advisory*
19 *Committee shall continue to operate through the end*
20 *of fiscal year 2019.*

21 *“(2) CONTINUATION IF NOT REAUTHORIZED.—If*
22 *at the end of fiscal year 2019 the duration of the Ad-*
23 *visory Committee has not been extended by statute,*
24 *the Advisory Committee may be deemed, for purposes*
25 *of the Federal Advisory Committee Act, an advisory*

1 *committee established by the President or an officer of*
2 *the Federal Government under section 9(a) of such*
3 *Act.”; and*

4 *(6) by striking subsection (h) (relating to author-*
5 *ization of appropriations), as redesignated by para-*
6 *graph (3).*

7 **SEC. 5. CLEARINGHOUSE OF NEWBORN SCREENING INFOR-**
8 **MATION.**

9 *Section 1112 of the Public Health Service Act (42*
10 *U.S.C. 300b–11) is amended—*

11 *(1) in subsection (a)—*

12 *(A) in paragraph (2), by striking “and” at*
13 *the end;*

14 *(B) in paragraph (3)—*

15 *(i) by striking “data” and inserting*
16 *“information”; and*

17 *(ii) by striking the period at the end*
18 *and inserting a semicolon; and*

19 *(C) by adding at the end the following new*
20 *paragraphs:*

21 *“(4) maintain current information on the num-*
22 *ber of conditions for which screening is conducted in*
23 *each State; and*

24 *“(5) disseminate available evidence-based guide-*
25 *lines related to diagnosis, counseling, and treatment*

1 *with respect to conditions detected by newborn screen-*
2 *ing.”;*

3 (2) *in subsection (b)(4)(D), by striking “New-*
4 *born Screening Saves Lives Act of 2008” and insert-*
5 *ing “Newborn Screening Saves Lives Reauthorization*
6 *Act of 2014”;*

7 (3) *in subsection (c)—*

8 (A) *by striking “developing the clearing-*
9 *house” and inserting “carrying out activities”;*
10 *and*

11 (B) *by striking “clearinghouse minimizes*
12 *duplication and supplements, not supplants”*
13 *and inserting “activities minimize duplication*
14 *and supplement, not supplant”;* *and*

15 (4) *by striking subsection (d) (relating to author-*
16 *ization of appropriations).*

17 **SEC. 6. LABORATORY QUALITY AND SURVEILLANCE.**

18 *Section 1113 of the Public Health Service Act (42*
19 *U.S.C. 300b–12) is amended—*

20 (1) *in the section heading, by inserting “AND*
21 ***SURVEILLANCE*” before the period;**

22 (2) *in subsection (a)—*

23 (A) *in the matter preceding paragraph (1),*
24 *by striking “and in consultation with the Advi-*
25 *sory Committee” and inserting “and taking into*

1 *consideration the expertise of the Advisory Com-*
2 *mittee”;* and

3 *(B) in paragraph (1), by inserting “timeli-*
4 *ness for processing such tests,” after “newborn-*
5 *screening tests,”;* and

6 *(3) by striking subsection (b) (relating to author-*
7 *ization of appropriations) and inserting the fol-*
8 *lowing:*

9 *“(b) SURVEILLANCE ACTIVITIES.—The Secretary, act-*
10 *ing through the Director of the Centers for Disease Control*
11 *and Prevention, and taking into consideration the expertise*
12 *of the Advisory Committee on Heritable Disorders in*
13 *Newborns and Children established under section 1111, may*
14 *provide, as appropriate, for the coordination of surveillance*
15 *activities, including—*

16 *“(1) through standardized data collection and re-*
17 *porting, as well as the use of electronic health records;*
18 *and*

19 *“(2) by promoting data sharing regarding new-*
20 *born screening with State-based birth defects and de-*
21 *velopmental disabilities monitoring programs.”.*

22 **SEC. 7. INTERAGENCY COORDINATING COMMITTEE ON**
23 **NEWBORN AND CHILD SCREENING.**

24 *Section 1114 of the Public Health Service Act (42*
25 *U.S.C. 300b–13) is amended—*

1 (1) *in subsection (c), by striking “the Adminis-*
2 *trator, the Director of the Agency for Healthcare Re-*
3 *search and Quality,” and inserting “the Adminis-*
4 *trator of the Health Resources and Services Adminis-*
5 *tration, the Director of the Agency for Healthcare Re-*
6 *search and Quality, the Commissioner of Food and*
7 *Drugs,”; and*

8 (2) *by striking subsection (e) (relating to author-*
9 *ization of appropriations).*

10 **SEC. 8. NATIONAL CONTINGENCY PLAN FOR NEWBORN**
11 **SCREENING.**

12 *Section 1115(a) of the Public Health Service Act (42*
13 *U.S.C. 300b–14(a)) is amended—*

14 (1) *by striking “consortia” and inserting “con-*
15 *sortium”;* and

16 (2) *by adding at the end the following: “The*
17 *plan shall be updated as needed and at least every*
18 *five years.”.*

19 **SEC. 9. HUNTER KELLY RESEARCH PROGRAM.**

20 *Section 1116 of the Public Health Service Act (42*
21 *U.S.C. 300b–15) is amended—*

22 (1) *in subsection (a)(1)—*

23 (A) *in subparagraph (B), by striking “;*
24 *and” and inserting a semicolon;*

1 (B) by redesignating subparagraph (C) as
2 subparagraph (E); and

3 (C) by inserting after subparagraph (B) the
4 following:

5 “(C) providing research findings and data
6 for newborn conditions under review by the Ad-
7 visory Committee on Heritable Disorders in
8 Newborns and Children to be added to the rec-
9 ommended uniform screening panel;

10 “(D) conducting pilot studies on conditions
11 recommended by the Advisory Committee on
12 Heritable Disorders in Newborns and Children
13 to ensure that screenings are ready for nation-
14 wide implementation; and”;

15 (2) in subsection (c), by striking “of the National
16 Institutes of Health Reform Act of 2006”.

17 **SEC. 10. AUTHORIZATION OF APPROPRIATIONS.**

18 Part A of title XI of the Public Health Service Act
19 (42 U.S.C. 300b–1 et seq.) is amended by adding at the
20 end, the following:

21 **“SEC. 1117. AUTHORIZATION OF APPROPRIATIONS FOR**
22 **NEWBORN SCREENING PROGRAMS AND AC-**
23 **TIVITIES.**

24 “*There are authorized to be appropriated—*

1 “(1) to carry out sections 1109, 1110, 1111, and
2 1112, \$11,900,000 for each of fiscal years 2015
3 through 2019; and

4 “(2) to carry out section 1113, \$8,000,000 for
5 each of fiscal years 2015 through 2019.”.

6 **SEC. 11. REPORTS TO CONGRESS.**

7 (a) *GAO REPORT ON TIMELINESS OF NEWBORN*
8 *SCREENING.*—

9 (1) *IN GENERAL.*—Not later than 2 years after
10 the date of enactment of this Act, the Comptroller
11 General of the United States shall submit a report to
12 the Committee on Health, Education, Labor, and
13 Pensions of the Senate and the Committee on Energy
14 and Commerce of the House of Representatives con-
15 cerning the timeliness of screening for heritable dis-
16 orders in newborns.

17 (2) *CONTENTS.*—The report submitted under
18 paragraph (1) shall include the following:

19 (A) An analysis of information regarding
20 the timeliness of newborn screening, which may
21 include the time elapsed from birth to specimen
22 collection, specimen collection to receipt by lab-
23 oratory, specimen receipt to reporting, reporting
24 to followup testing, and followup testing to con-
25 firmed diagnosis.

1 (B) *A summary of any guidelines, rec-*
2 *ommendations, or best practices available to*
3 *States and health care providers intended to sup-*
4 *port a timely newborn screening system.*

5 (C) *An analysis of any barriers to main-*
6 *taining a timely newborn screening system*
7 *which may exist and recommendations for ad-*
8 *ressing such barriers.*

9 (b) *REPORT BY SECRETARY.—*

10 (1) *IN GENERAL.—The Secretary of Health and*
11 *Human Services shall—*

12 (A) *not later than 1 year after the date of*
13 *enactment of this Act, submit to the Committee*
14 *on Health, Education, Labor, and Pensions of*
15 *the Senate and the Committee on Energy and*
16 *Commerce of the House of Representatives a re-*
17 *port on activities related to—*

18 (i) *newborn screening; and*

19 (ii) *screening children who have or are*
20 *at risk for heritable disorders; and*

21 (B) *not less than every 2 years, submit to*
22 *such committees an updated version of such re-*
23 *port.*

24 (2) *CONTENTS.—The report submitted under this*
25 *subsection shall contain a description of—*

1 (A) *the ongoing activities under sections*
2 *1109, 1110, and 1112 through 1115 of the Public*
3 *Health Service Act; and*

4 (B) *the amounts expended on such activi-*
5 *ties.*

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